

**PRODUCT PREPARATION SHEET: NON-GMP RECOMBINANT HUMAN  
INTERLEUKIN-6, Lot # L0406011**

**DESCRIPTION**

Recombinant human IL-6 (rHu IL-6) is a potent, multifunctional lymphoid cell growth factor that affects a variety of immune and hybridoma cells. The IL-6 is supplied as a sterile, lyophilized product for reconstitution with Sterile Water for Injection, USP. Each reconstituted vial contains 0.2 mg of non-GMP IL-6 at a concentration of 0.4 mg/ml with 10 mM sodium phosphate and 2% mannitol. The reconstituted solution is clear and colorless.

**RECONSTITUTION OF LYOPHILIZED RECOMBINANT HUMAN INTERLEUKIN-6**

**Caution: Contains no preservatives. Single-use vial. Do not reenter vial. Use within 12 hours after reconstitution and heating.**

**PROCEDURE**

**Caution: Use aseptic technique. Calculate the dose and the number of vials required.**

- Materials:
- 1) rHu IL-6, lot # L0406011 @ 0.2 mg/vial
  - 2) Sterile Water for Injection (WFI), USP (i.e., Sterile Water for Injection, USP, 10 ml, NDC-0074-4887-10, from Abbott Laboratories, North Chicago, IL, 60064)
  - 3) 1 ml sterile syringe (2)
  - 4) 21 gauge needle to fit 1 ml syringe (2)
  - 5) Alcohol wipes or equivalent
  - 6) a. Calibrated heating device (i.e., water bath or heating block) capable of heating to 50 °C with 2 °C accuracy, **OR**  
b. Calibrated temperature-measuring device (i.e., thermometer) capable of measuring to 50 °C with 2 °C accuracy **AND** a suitable reservoir (i.e., water bath) to accommodate the vials(s) being prepared and allow accurate measurement of temperature. Insure that water (or other heating liquid) **DOES NOT** contact vial septum during incubation period (potential source of contamination).
  - 7) NIST-traceable timer with an accuracy of 1 minute.
- Turn on heating unit to allow sufficient time for temperature reading to stabilize at 50 ± 2 °C.
  - Remove product vial from refrigerator.
  - Decontaminate the exterior of the product vial crimp and WFI vial crimp with an alcohol wipe. Let air dry.
  - Remove the crimp septum cover.
  - Sanitize the rubber septum of the product vial with an alcohol wipe and allow it to dry.

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- Aseptically remove 0.5 ml from the WFI container using a 21 gauge needle with the 1 ml syringe.
- Holding the syringe plunger, insert the needle through the product vial septum and inject the WFI. Angle the needle away from cake to avoid foaming.
- Swirl the dissolved rHu IL-6 solution GENTLY. Avoid foaming the solution. **DO NOT SHAKE.** The product should form a clear, colorless solution within 5 minutes.
- Place the vial of reconstituted rHu IL-6 into the heating unit. Insure that the vial does not tip over. **DO NOT** allow liquid (if used) to contact vial stopper.

**Caution: The vial must be in good thermal contact with the heating unit. Any portions of the vial not exposed to heating fluid (if used), or surrounded by “dead” air space will not be efficiently heated.**

- Heat the vial of reconstituted rHu IL-6 for  $10 \pm 2$  minutes at  $50 \pm 2$  °C. Avoid exposure of vial septum with any heating fluid (i.e., water).
- Remove vial from heating unit. Clean vial and septum with an alcohol wipe.
- Inspect reconstituted IL-6 for foreign/particulate matter. Liquid within vial should be clear and colorless.
- Use a new syringe and needle to aseptically remove reconstituted material from the vial for patient administration.

**STORAGE AND STABILITY INFORMATION**

Prior to Reconstitution

Lyophilized rHu IL-6 should be stored in a refrigerator between 2 to 8°C (36 to 46°F). Do not freeze.

Reconstituted Vials

If the vial of reconstituted and heated rHu IL-6 is not used immediately, it may be held at controlled room temperature 15 to 30°C (59 to 86°F) or refrigerated between 2 to 8 °C (36 to 46°F) but must be used within 12 hours. Avoid exposing rHu IL-6 solutions to heat and/or direct sunlight. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Product Stability

Analytical size exclusion chromatography data and cell proliferation assays have shown that reconstituted rHu IL-6 is stable for at least 12 hours following the reconstitution and heating procedure described above.

**HOW SUPPLIED**

rHu IL-6 is supplied as 0.2 mg of sterile, white, preservative-free lyophilized powder in sterile, single-use vials.

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**USE RESTRICTIONS**

**rHu IL-6, lot # L0406011 is restricted to *in vitro* use or use in GLP animal studies.  
This material is NOT for use in humans.**

**CONTACT INFORMATION**

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